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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/826,893 | 04/06/2001 | Kjell Olmarker | 003300-765 | 3406 |

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| EXAMINER |
|---|
| O HARA, EILEEN B |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/826,893 | OLMARKER ET AL. | |
| | Examiner | Art Unit | |
| | Eileen O'Hara | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 December 2003 and 12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16,18,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Withdrawal of Final Rejection*

1. The final rejection is hereby withdrawn and prosecution is re-opened to reinstate the rejections under 35 USC § 102 and § 103 and new rejection under § 103.

### *Status of Claims*

2. Claims 1-16, 18, 30 and 31 are pending in the instant application. Claim 1 has been amended and claims 20-23 and 25-28 have been canceled as requested by Applicant in the Paper filed December 8, 2003.

All claims are currently under examination.

### *Withdrawn Rejections*

3. The rejections of claims under obviousness-type double patenting and 112 § 2 are withdrawn in view of Applicants' terminal disclaimer and amendment.

### *Claim Objections*

4. Claim 31 is objected to because of the following informalities: at the end of the claim, SH should be SH-636. Appropriate correction is required.

### *Declaration under 37 CFR 1.131*

5. The Declaration filed on May 22, 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Tobinick, US Patent No. 6,419,944 reference. The reference is a U.S. patent that claims the rejected invention. An affidavit or declaration is inappropriate under

37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

## *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The effective priority date of the instant application is the filing date, April 6, 2001, since the claims are limited to a method of treatment with CDP-870, and this method was not disclosed in any of the priority documents.

5. Claims 1-16, 18 and 30 are rejected under 35 U.S.C. 102(e) as being unpatentable over Tobinick, US Patent No. 6,419,944, filing date April 5, 2001, for reasons of record in the Office Action, Paper No. 16, at pages 5-6. Claims 1-16, 18 and 30 encompass a method for inhibiting the action of TNF-$\alpha$ for treating nerve disorders in a subject, which may be vertebrate, mammal or human, comprising administering the TNF-$\alpha$ inhibitor CDP-870 or D2E7, wherein the nerve

disorder is a spinal disorder (which may be spinal cord compression), nerve root injury, sciatica, caused by herniated discs, involves pain, is nucleus pulposus-induced nerve injury, and wherein the TNF-$\alpha$ inhibitor is administered systemically, locally, parenterally, intramuscularly, intravenously by injection or infusion, subcutaneously, orally at a dosage of about 20 mg to about 1,500 mg, rectally, or administered at a dosage of about 1 mg/kg to about 50 mg/kg body weight of said subject.

Tobinick teaches that antagonists to tumor necrosis factor can be used to treat nerve disorders in humans, which may be due to a herniated nucleus pulposus, including damage to the spinal cord (compression), nerve roots, herniated discs and sciatica, and that one such antagonist which may be used is CDP 870 and D2E7, (see entire patent and claims, especially column 2, line 1 to column 3, line 20, column 5, lines 58-65, and claims 21, 33 and 35 and column 8, lines 58-60). Tobinick also teaches that the antagonist may be administered locally (subcutaneously, column 5, lines 8-15), and the dosage can be between 1 and 300 mg (see column 10, line 29 to column 11, line 5 and claim 12). Therefore, Tobinick anticipates the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7.1 Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tobinick, US Patent No. 6,419,944, and further in view of Bourrie et al., European Journal of Immunology, Vol. 25, pages 2882-2887, 1995.

Claim 31 encompasses a method for inhibiting the action of TNF-$\alpha$ for treating nerve disorders in a subject comprising administering the TNF-$\alpha$ inhibitor SR 31747A. The teachings of Tobinick are discusses above. Tobinick does not teach that SR 31747A can be used in the method to treat nerve disorders.

Bourrie et al. teaches that SR 31747A inhibits the systemic release of TNF-$\alpha$.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use SR 31747A in the method of treatment of nerve disorders as taught by Tobinick, because Bourrie et al. teaches that it inhibits the release of TNF-$\alpha$. The skilled artisan would be motivated to do so, because this drug may be as or more effective than other TNF-$\alpha$ inhibitors, and different subjects respond differently to the same drugs. Therefore, in some individuals this drug may be more effective and have fewer side effects than other drugs. There would be a reasonable expectation of success, since Bourrie teaches that the drug is effective in mice.

7.2 Claims 1-16, 18, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobinick et al., U.S. Patent No. 6,015,557, effective priority date Feb. 24, 1999, and further in view of Bourrie et al., European Journal of Immunology, Vol. 25, pages 2882-2887, 1995 and Dhainaut et al., Critical Care Medicine, Vol. 23, No. 9, pages 1461-1469, Sept. 1995.

Tobinick et al. teaches a method for treating neurological conditions by administration of TNF antagonists, which disorders may be spinal disorder (which may be spinal cord compression), nerve root injury, sciatica, caused by herniated discs, involves pain, is nucleus pulposus-induced nerve injury, and wherein the TNF-$\alpha$ inhibitor is administered systemically, locally, parenterally, intramuscularly, intravenously by injection or infusion, subcutaneously, orally at a dosage of about 20 mg to about 1,500 mg, rectally, or administered at a dosage of about 1 mg/kg to about 50 mg/kg body weight of said subject (see column 3, line 61 to column 4, line 10, column 1, lines 35-47, column 3, lines 10-24, and especially the claims). Tobinick et al. do not teach that the TNF-$\alpha$ inhibitor is CDP-571 or SR 31747A.

Bourrie et al. teaches that SR 31747A inhibits the systemic release of TNF-$\alpha$.

Dhainaut et al. teaches that CDP-571 is a TNF-alpha receptor antagonist, and is well tolerated and able to cause a dose-dependent reduction in circulating TNF-alpha concentrations in patients with septic shock. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use SR 31747A or CDP-571 in the method of treatment of nerve disorders as taught by Tobinick, because Bourrie et al. teaches that it inhibits the release of TNF-$\alpha$, and De Lacharriere et al. teaches that CDP-571 is a TNF-alpha receptor antagonist. The skilled artisan would be motivated to do so, because these drugs may be as or more effective than other TNF-$\alpha$ inhibitors, and different subjects respond differently to the

same drugs. Therefore, in some individuals this drug may be more effective and have fewer side effects than other drugs. There would be a reasonable expectation of success, since Bourrie teaches that SR 31747A is effective in mice, and CDP-571 is effective in humans.

## *Conclusion*

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner